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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,503	06/07/2001	Hiroshi Oda	11283-009001	1563

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,503	ODA ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed June 6, 2005 is acknowledged and has been entered.

Remarks

It is noted that the Examiner previously indicated allowable subject matter and that the Applicant has amended the claims to include this subject matter. However, upon further consideration the claims are not deemed Allowable (see action below). Examiner apologizes for any inconvenience caused to Applicant.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is vague and indefinite because it is unclear how determining the concentration of creatinine is correlated with increased levels of L-PGDS, and also how determining the concentration of creatinine correlates with the method as recited. The method merely calls for the determination of serum creatinine. There is no positive recitation correlating this determination to an early-stage renal disease. Does a normal serum creatinine and a higher concentration of L-PGDS indicate early-renal disease. How does an increased level of serum creatinine effect the method?

Claim 38 is vague and indefinite because it is unclear how determining the test subject not to be exhibiting proteinuria is correlated with increased levels of L-PGDS, and also how determining the test subject not to be exhibiting proteinuria correlates with the method as recited. The method merely calls for the determination that the test subject not be exhibiting proteinuria. There is no positive recitation correlating this determination to an early-stage renal disease. Does the test subject not exhibiting proteinuria and a higher concentration of L-PGDS indicate early-renal disease?

Claim 39 is vague and indefinite because it is unclear how determining the concentration of albumin in the urine of the test subject to be normal is correlated with increased levels of L-PGDS, and also how determining the concentration of albumin of the test subject to be normal correlates with the method as recited. There is no positive recitation correlating this determination to an early-stage renal disease. Does a normal albumin urine level and a higher concentration of L-PGDS indicate early-renal disease?

Claim 40 is vague and indefinite because it is unclear how determining the concentration of creatinine in the serum of the test subject to be normal, the concentration of albumin in the urine to be normal and the test subject not exhibiting proteinuria is correlated with increased levels of L-PGDS, and also how determining the concentration of creatinine in the serum of the test subject to be normal, the concentration of albumin in the urine to be normal and the test subject not exhibiting proteinuria correlates with the method as recited. There is not positive recitation correlating these determinations to an early-stage renal disease. Does a normal serum

creatinine, normal albumin urine level, the test subject not exhibiting proteinuria and a higher concentration of L-PGDS indicate early-renal disease?

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 37 - 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al (Molecular characterization of beta-trace protein in human serum and urine: a potential diagnostic marker for renal disease, Gylcobiology, vol 7, no 4 p 499-506 (1997)) in view of Katzberg et al (US 6,122,540).

Hoffman et al disclose that beta-trace protein (lipocalin-type prostaglandin D synthase (L-PGDS)) was isolated from cerebrospinal fluid, serum, plasma and urine samples of normal volunteers and sera and hemofiltrate of patients with chronic renal failure (abstract). Hoffman et al disclose that serum L-PGDS concentration in patients with end-stage renal failure increased as compared to the L-PGDS of the normal volunteers. Hoffman et al disclose that serum beta-trace (L-PGDS) concentrations were determined by quantitative immunoaffinity chromatography in conjunction with amino acid sequencing and SDS gel electrophoresis and revealed a broad range of concentrations (p. 504, col 2, lines 36-60).

Even tough Hoffman et al is silent on a method of detection of an early-stage renal disease, Hoffman et al teaches that beta-trace protein (L-PGDS) accumulates more significantly in serum in pathological conditions than other proteins in current use and that the beta-trace protein may be used for the study and early diagnosis of renal diseases (p. 505, lines 14-21). Therefore, it would have been obvious to one of ordinary skill in the art to have a reasonable expectation of success to use the method of Hoffman et al for the detection of early-stage renal disease.

With respect to a urine sample as recited in the instant claims. Hoffman et al disclose that the proteins of urinary and serum-derived beta-trace proteins are identical

(p. 501 and 504) and Hoffman et al further teaches the detection of beta-trace proteins in urine. Hoffman et al specifically teaches that in renal diseases that the elimination of proteins through the kidney is disturbed resulting in elevated concentrations of proteins and Hoffman et al also teaches higher levels of L-PGDS in renal failure patients. Therefore, it would have been obvious to one of ordinary skill in the art to use urine as the sample for beta-trace proteins. Further, Hoffman et al also teaches that proteins are elevated in renal disease, and that L-PDGS may be used for the study and early diagnosis of renal diseases, Therefore, one of ordinary skill in the art would expect increased levels of L-PGDS in the urine of renal disease patients and one of ordinary skill in the art would have a reasonable expectation of success to use urine as a sample and use the method of Hoffman et al for the detection of early-stage renal disease.

Hoffman et al differ from the instant invention in failing to teach determining the concentration of creatinine in the serum of the test subject to be normal and also testing the patient for albumin and proteinuria.

Katzberg et al teaches that even in patients with renal insufficiencies that creatinine levels can be normal (col 1, lines 24-28).

It would have been obvious to one of ordinary skill in the art to apply the method of Hoffman et al to either kidney diseased patient or a normal patient as taught by Katzberg et al since Katzberg teaches that even in patients with renal insufficiencies that creatinine levels can be normal. Further, it would have also been obvious to one or ordinary skill in the art to determine the concentration of albumin and proteinuria

because it is known in the art that albumin and proteinuria are associated with kidney disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
July 28, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
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08/03/05